

**REMARKS**

Prior to the present amendment, claims 47-57 were pending. By the present amendment, applicants have canceled claims 52 and amended claims 48, 49, and 57. No new matter has been added by these amendments. Accordingly, claims 47-51 and 53-57 are under examination.

**Rejection of claims 47-50 and 53-56 under 35 U.S.C. § 102(b)**

On page 3 of the office action, the examiner rejects claims 47-50 and 53-56 under 35 U.S.C. § 102(b) in view of Fraser, et al. (WO 99/57280). On page 5 of the office action, the examiner states that "Applicant may obviate the rejection by reciting that the 'recombinant protein consists of the amino acid sequence set forth in SEQ ID NO: 4.'"

Applicants thank the examiner for providing a suggested amendment. Applicants have amended the claims accordingly, and submit that the Fraser reference fails to teach each and every element of the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection of claims 47-56 under 35 U.S.C. § 103(a) in view of the Fraser and Tai references**

On page 7 of the office action, the examiner rejects claims 47-56 under 35 U.S.C. § 103(a) as being unpatentable over Fraser, et al (WO 99/57280) in view of Tai, et al (WO 97/28273).

Applicants respectfully disagree. Fraser fails to teach or disclose a protein consisting of the sequence set forth in SEQ ID NO: 4. The Tai reference fails to rectify the deficiencies of Fraser because it also fails to teach or disclose a protein consisting of the sequence set forth in SEQ ID NO: 4.

Accordingly, a *prima facie* case of obviousness has not been made since the claimed invention as a whole would not have been known or obvious to one having ordinary skill in the art at the time of the invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 112, first paragraph**

On page 10 of the office action, the examiner rejects claims 52 and 57 under 35 U.S.C. § 112, first paragraph. Applicants have canceled claim 52, thereby rendering the rejection moot.

With respect to claim 57, the examiner asserts that the specification does not disclose the claimed invention. Applicants respectfully disagree. Support for the claimed invention may be found, for example, in the abstract, last sentence, wherein the Applicants state that the “resultant formulations of this invention are of use in the pharmaceutical industry as vaccine formulations for human use.” One of the resultant formulations disclosed in the application is the claimed fusion protein. For example, Applicants state on page 14, lines 9-10 that “The final construction is showed in Figure 2, and the NMB0928 protein is expressed as a fusion protein to the Nt-segment of P64 kDa protein.” On page 10 of the specification, the Applicants explain that the “final construction of nucleotide sequence of the gene *NMB0928*” is shown in Figure 2. Figure 2 illustrates the vector used to construct the NMB0928 fusion protein, which includes the N-terminus of P64k. In Example 10, Applicants state that the “[NMB0928 protein] is recognized by human sera, “which indicates that [NMB0928 protein] is expressed during the meningococcal infection and it is immunogenic.” Accordingly, the claimed invention does not recite new matter.

Accordingly, applicants respectfully request reconsideration and withdrawal of the rejections.

**Rejection under 35 U.S.C. § 112, second paragraph**

On page 12 of the office action, the examiner rejects claim 52 and 57 under 35 U.S.C. § 112, second paragraph. As stated above, claim 52 is canceled, thereby rendering the rejection moot. Claim 57 has been amended to clarify what structure is included in the N-terminus of the P64k protein and how many acids. Support for the amendment is found on page 13, lines 20-22, which describes a “gene segment codifying for the 47 amino acid stabilizing sequence from Nt-fragment of P64 kDa from *Neisseria meningitidis*.”

Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection of claim 57 under 35 U.S.C. § 103(a) in view of the Fraser and Cano**

On page 14 of the office action, the examiner rejects claim 57 as being unpatentable under 35 U.S.C. § 103(a) over the Fraser reference and Cano reference (US 6146635). Applicants respectfully disagree. As stated above, the Fraser reference fails to teach or disclose a protein consisting of the sequence set forth in SEQ ID NO: 4. The Cano reference fails to rectify the deficiencies of Fraser because it also fails to teach or disclose a protein consisting of the sequence set forth in SEQ ID NO: 4.

Accordingly, a *prima facie* case of obviousness has not been made since the claimed invention as a whole would not have been known or obvious to one having ordinary skill in the art at the time of the invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Conclusion**

In view of the foregoing amendments and remarks, entry of the amendments and favorable consideration of the claims are respectfully requested. If the examiner has any questions or concerns regarding this amendment, he or she is invited to contact the undersigned at the telephone number listed below. If any fees are due or any overpayment made in connection with this paper, please charge or credit our Deposit Account No.: 082461 for such sum.

Respectfully submitted,

/anna c. chau/  
Anna C. Chau  
Registration No: 54,637  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike, Suite 200  
Syosset, New York 11791  
(516) 822-3550  
ACC:  
329696\_1.DOC